BEFORE THE BOARD OF PHARMACY
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of ARM 24.174.301 and 24.174.303 definitions, 24.174.401 and 24.174.403 general provisions, 24.174.503, 24.174.514, 24.174.521, 24.174.522, 24.174.523, and 24.174.524 licensing, 24.174.603 and 24.174.612 internship regulations, 24.174.705 and 24.174.711 pharmacy technicians, 24.174.801, 24.174.806, and 24.174.814 certified pharmacies, 24.174.1002 mail service pharmacies, 24.174.1107 and 24.174.1111 institutional pharmacies, 24.174.1201, 24.174.1202, 24.174.1211, and 24.174.1212 wholesale drug distributors licensing, 24.174.1401 dangerous drugs, 24.174.2101 renewals and continuing education, 24.174.2401 screening panel, and the adoption of NEW RULE I inactive license, NEW RULE II telepharmacy operations, NEW RULE III remote telepharmacy dispensing machine sites, NEW RULE IV central filling by hub pharmacies, NEW RULE V ambulatory surgical facilities, and NEW RULE VI fee abatement	)	NOTICE OF AMENDMENT AND ADOPTION

TO: All Concerned Persons

1. On January 12, 2006, the Board of Pharmacy (board) published MAR Notice No. 24-174-54 regarding the public hearing on the proposed amendment and adoption of the above-stated rules, at page 23 of the 2006 Montana Administrative Register, issue no. 1.

2. On February 2, 2006, a public hearing was held on the proposed amendment and adoption of the above-stated rules in Helena. Four individuals testified at the hearing and written comments were received by the February 10, 2006, deadline.

3. The board has thoroughly considered the comments and testimony received. A summary of the comments received and the board's responses are as follows:

COMMENT 1: Several comments were received supporting specific rules in this rulemaking notice.

RESPONSE 1: The board acknowledges the comments.

COMMENT 2: A commenter requested an extension of the comment period because the board did not provide him with documentation of studies that failed to link incidence of medication errors to pharmacist-to-technician ratios.

RESPONSE 2: The commenter was provided with the information the board had reviewed in changing this rule prior to the comment period ending and was offered the opportunity to present comments, but no further comments were received from that commenter.

COMMENT 3: One commenter stated that the board is required to give 60 days' notice prior to rule changes and requested the board respect the requirement.

RESPONSE 3: The Montana Administrative Procedure Act (MAPA) requires all executive agencies proposing administrative rule changes give a minimum of 20 days' notice of a public hearing, 28 days' notice for public comments, and 30 days between notice and the agency or board's final action. These timelines all begin with the publication date of the rule notice in the Montana Administrative Register. The board does not have different rulemaking notice requirements than those provided by MAPA. The board's notices have fulfilled the statutory requirements. The board notes that approximately five months have elapsed between the publication of the proposed rule changes and the publication of this notice of final action.

COMMENT 4: A comment was received regarding several terms. "Externship" should be replaced with "introductory pharmacy practice experiences" and "clerkship" which is proposed to be deleted, but the replacement term of "advanced practice" is incomplete and should be replaced with "advanced pharmacy practice experiences."

RESPONSE 4: The board agrees with the suggestion and has amended the rule to place those terms in ARM 24.174.303.

COMMENT 5: A comment was received asking the board to amend ARM 24.174.303(6) to not require 20 internship hours per week and instead set some monthly hour requirement and allow hours to be split among sites.

RESPONSE 5: Because the board did not propose changing the 20-hour per week internship provisions, the board believes that it cannot properly make the suggested change as part of this rulemaking project. All substantive changes to the board's rules must go through the publication and comment process required by MAPA for rulemaking. The board will consider the request when contemplating future rulemaking projects.

COMMENT 6: A question was received regarding ARM 24.174.503 as to who would be certifying interns for administering immunizations. The commenter asked if the board would acknowledge the School of Pharmacy's process for certifying, or if the board would just have its own process.

RESPONSE 6: The board believes that with the current level of pharmacy education, virtually all students are coming out of their training immunization certified. Immunizations being administered by pharmacies are done so under a collaborative practice agreement with a physician that must be approved by the board annually. The interns are working under the direct supervision of the pharmacist in charge involved in the collaborative practice agreement.

COMMENT 7: Comments were received requesting amending ARM 24.174.521 so that only pharmacies "certified" by the board to take back medications may reuse them.

RESPONSE 7: Making the changes to this rule as proposed by the commenter would need to be noticed for public comment in a future rule notice. The board will consider the request when contemplating future rulemaking projects.

COMMENT 8: A comment was received that the term "certified pharmacy" should not be stricken in ARM 24.174.522.

RESPONSE 8: The board acknowledges the comment. Although the term “certified pharmacy" is used in statute, the board does not have a different license classification for a "certified" pharmacy versus any other pharmacy. The word "certified” was used in some areas of board rules but not others and is not included in the definitions. Removal of the term in rules addresses those disparities.

COMMENT 9: A commenter expressed concern at a dichotomy between the board's responsibility in ARM 24.174.603 and the proposed shift of school responsibilities in ARM 24.174.612.

RESPONSE 9: In light of the comments received, the board has decided not to amend ARM 24.174.612.

COMMENT 10: Comments were received that the handling of internship forms should remain a board requirement/function and not that of the School of Pharmacy. The comments indicated that educational institutions would not accept responsibility for tracking and handling of internship hours, that those institutions were not staffed to track such time, and that the institutions would be unable to verify certain aspects of the information required to be included in the internship documents.

RESPONSE 10: In light of the comments received, the board has decided not to amend ARM 24.174.612.

COMMENT 11: A comment was received on the existence of the approved utilization plan as it ties to the ratio amendments proposed in ARM 24.174.711.

RESPONSE 11: If a pharmacy currently has a Technician Utilization Plan that is stricter than board rule, it may keep those restrictions in place. In any case, the proposed change in ratio does not change the requirement that a pharmacy

complete a Technician Utilization Plan for board review in order to implement the use of pharmacy technicians.

COMMENT 12: Comments were received from both proponents and opponents regarding the proposed amendment of the ratio of pharmacy technicians to supervising pharmacists in ARM 24.174.711.
Comments received in favor of the change stated that:

(a) the 1:4 pharmacist to technician ratio is just fine;

(b) to preserve patient safety and public trust, the 1:4 pharmacist to technician ratio should include any technicians, interns and/or externs; and

(c) that a pharmacist should never supervise more than four people.

Opponents stated that:

(a) the 4:1 technician to pharmacist ratio is not in the best interest of public safety and stated that the board already has a process in place that allows for variation of the 1:1 ratio;

(b) the majority of other state boards do not allow a 4:1 ratio; and

(c) the 4:1 ratio goes too far and is not in the public's best interest.

One pharmacist felt he could not supervise four techs at one time and believes the increased ratio will decrease pharmacy school applications and ultimately lead to prescription dispensing by technicians alone and feels the public will suffer as a result. Three commenters suggest a ratio of 2:1, or no greater than 3:1.

RESPONSE 12: The board acknowledges the comments. Following discussion of the comments and upon deliberation, the board has amended the rule to decrease the ratio to one pharmacist to three pharmacy technicians on the basis of the testimony from licensed pharmacists as to the likely harm to the public health and safety and in consideration of the regulatory decisions of sister boards in other states.

COMMENT 13: There were several comments received concerning the proposed amendments to ARM 24.174.801 pertaining to pharmacy benefits managers.

RESPONSE 13: During final preparation of this Notice of Amendment and Adoption, board staff noticed a potentially significant ambiguity in the language of proposed (7). In order to clarify the board's intent with respect to proposed (7), the board will meet via telephone conference call to discuss the impact of the apparent ambiguity and decide upon final action with respect to proposed (7) in light of the apparent ambiguity. Accordingly, the board is not taking final action on ARM 24.174.801 at this time. The board will, at a later date, give separate notice of its final decision with respect to the proposed amendments to ARM 24.174.801, and provide a more detailed summary of the comments received on that rule.

COMMENT 14: A comment was received cautioning against striking "certified" from the catchphrase of ARM 24.174.814, and suggested the board create a common

definition for what is intended as a "perpetual inventory," and address what must be done if the count is off.

RESPONSE 14: Please see Response 8 regarding the term “certified”. The board appreciates the comment on perpetual inventory. The board believes that pharmacies should have some latitude in how they practice. The board notes that the term "perpetual inventory" means the practice of maintaining some quantity of drugs of a particular class that the pharmacy will make sure that it has on hand at all times, regardless of the typical or expected demand for that particular drug. It also includes the breadth of the range of drugs within that schedule which the pharmacy strives to keep in stock at all times. The board also notes that the term "perpetual inventory" can be used to describe the process of conducting a count of the units of a given drug on hand, and comparing that number to the number of units that the pharmacy's records indicate should be present. In ARM 24.174.814, the term refers to the inventory (counting) process. The board has concluded that it is not necessary to require that all pharmacies conduct such an inventory on a schedule mandated by the board, and that individual pharmacies are in the best position to determine the appropriate timing of those counts. The board’s inspector is charged with reviewing inventory each inspection. The board has asked the inspector to keep a log of visits and the various types and time frames involved in inventories at present, and will review that log to determine the need for any future adjustments to the rule. The board is comfortable with the present definition of perpetual inventory and with pharmacists using their professional judgment.

With respect to the question of what to do if there is an unexplained discrepancy detected during an inventory of scheduled drugs, the pharmacy has an obligation to disclose that fact to the appropriate regulatory agencies, such as the board and the DEA.

COMMENT 15: A comment was received that perpetual inventories are a recognized standard of "practice" not "care," as was stated in the reasonable necessity statement for this rule.

RESPONSE 15: The board acknowledges the comment and agrees with the point raised. The board regrets its inadvertent erroneous use of terminology.

COMMENT 16: Comments were received regarding ARM 24.174.1107. A commenter suggested clarifying whether nonpharmacy personnel are allowed in a closed pharmacy, or if those persons can only access a night cabinet.

RESPONSE 16: The rule is specifically addressing the absence of a pharmacist in an institutional setting and the use of “night cabinets” or nonpharmacy storage areas of medications. The board acknowledges that the absence of a pharmacist in institutional settings is difficult during night hours and weekends. The board agreed to alter the 48-hour reference for consulting with a pharmacist to 72 hours in order to give more time for consulting with a pharmacist, especially for those facilities in rural areas. However, the board does not believe that the standard of care should be less

in one part of the state than another. Good patient care dictates that verification audits and chart review for any changes to a patient's medication be reviewed by a pharmacist as soon as possible following the administration of drugs obtained from a night cabinet.

COMMENT 17: A commenter expressed confusion on the definition of "institutional pharmacy" and questioned whether an "institutional pharmacy" is a medication room or a closet/cabinet/medication cart.

RESPONSE 17: The board acknowledges that many institutions, such as detention facilities, do not have an institutional pharmacy per se. Some of those institutions use other methods for storing medication such as medication carts, closets, and locked boxes for storing medications that are inaccessible to unauthorized personnel.

COMMENT 18: A commenter requested clarification of ARM 24.174.1107(2) on prepackaged contents of night cabinets and whether it means packaged as a unit-of-use, versus packaged into a bottle or container containing the appropriate number of doses being dispensed.

RESPONSE 18: The board believes most use of night cabinets is for inpatient use after hours, with the exception of rural outpatient emergency rooms. To the greatest extent possible anything for outpatient use should be prepackaged, while anything intended for inpatient use should be packaged in the unit-of-use. The intent of prepackaging is to assure labeling as well as directions for use, which is especially important when being given to an outpatient for the off-premises administration of dosages of the drug. The intent is that a person obtaining drugs from a night cabinet not have to "count pills" and divide the contents of a package in order to dispense the correct dosage or number of doses. The board notes that anything removed from a night cabinet needs to be accounted for by a verification audit conducted by the contracting pharmacist.

COMMENT 19: A suggestion was received amending ARM 24.174.1107(3) to require audits completion within 72 hours of drug removal, instead of the currently required 48 hours, to accommodate weekends.

RESPONSE 19: The board accepts the suggestion and has amended the rule accordingly.

COMMENT 20: A commenter stated that for inpatients, a "medication administration record" is the document a nurse will use, not the patient medication profile.

RESPONSE 20: The board acknowledges the comment, but declines to make any changes to the proposal because the characteristics of the patient medical profile specified in ARM 24.174.1107(6) provide a licensee of the board of pharmacy with the information that licensee needs to appropriately conduct the required review. The board's rules are directed to the board's licensees, not the licensees of other

health care professions. The board recognizes that other health care providers may refer to certain documents by other names, which may vary from setting to setting, and thus concludes that specifying the elements of required information, rather than the type of document, is the more important aspect of the rule.

COMMENT 21: Comments were received suggesting making ARM 24.174.1111 applicable to all institutional facilities, including half-way houses, nursing homes, long-term care facilities, hospices, and residential assisted living facilities.

RESPONSE 21: It is appropriate for policies and procedures to be in place for any facility or institution that handles drugs for patient or resident use. The board is making these rules based on its charge of overseeing the safety of medications for the citizens of Montana. The Department of Public Health and Human Services (DPHHS) licenses most of the facilities mentioned in the comment and violations found by DPHHS are reported to the board and to other professional licensing boards involved.

COMMENT 22: A commenter also asked for a distinction to be made between requirements for dispensing devices at remote telepharmacy locations and those installed at facilities where individuals licensed to administer or prescribe medications are the ones accessing the dispensing devices.

RESPONSE 22: ARM 24.174.1111 is not applicable to telepharmacy locations or in settings other than those described in the rule. Remote telepharmacy sites are specific in their intent to provide services to rural areas that are underserved due to the absence of a pharmacy. Further distinction of the rules for remote sites versus other facilities will need to be addressed by the board in a future rule project.

COMMENT 23: A commenter requested the board consider accepting the current Securities and Exchange Commission (SEC) filing of wholesale distributors owned by publicly-held corporations, in lieu of "address, telephone number, and ownership percentage" requested by the proposed amendments to ARM 24.174.1202. The commenter stated that a copy of the SEC filing would preserve the security of the corporate officers and still assure Montanans of a dependable supplier.

RESPONSE 23: To the extent that the commenter is concerned about the personal safety of corporate officers because of the disclosure of the address and telephone number of each corporate officer, the board notes that nothing in the proposed amendments requires that the home address or home telephone number of an officer be disclosed. Because the sole objection to providing the information appears to be based on a concern for personal safety, the board concludes that because a business address and telephone number for each officer can be provided, there is no substantial reason to exempt publicly traded corporations from complying with the rule.

COMMENT 24: A commenter suggested amending ARM 24.174.1211(8) to read [new matter underlined]: (w)ithin any calendar month, a wholesaler, not owned by a

publicly-traded manufacturer, may not sell, distribute, transfer, or otherwise provide more than 10% of the total amount distributed of each prescription drug or drug product to another wholesaler, distributor, or manufacturer." The commenter stated that the suggested seems to preserve the rule's intent while allowing the company to move products in large volumes through a few vaccine distributors on seasonal basis.

RESPONSE 24: The board considered the possibility of vaccines for instance, needing to be shipped in great quantities. If there were an emergency need of flu vaccine for instance, rules could be waived under such circumstances by the appropriate authorities in dealing with what it is in the best interest of the public. However, based upon the comments received, the board has decided not to include sections (8) and (9) in the final version of ARM 24.174.1211.

COMMENT 25: A commenter suggested amending ARM 24.174.1211(8) to read [new matter underlined]: "(w)ithin any calendar month, a wholesaler may not sell, distribute, transfer, or otherwise provide more than 10% of the total amount distributed of each prescription drug or drug product to another wholesaler, distributor, or manufacturer. This provision does not apply to distributions, sales or transfers between wholesalers under common ownership." The commenter stated that the suggested language would clarify that the restriction does not apply to intracompany transfers.

RESPONSE 25: The board acknowledges the comment. Based upon the comments received, the board has decided not to include sections (8) and (9) in the final version of ARM 24.174.1211.

COMMENT 26: A commenter suggested amending ARM 24.174.1211(9) to read [new matter underlined]: "(a) wholesaler may not purchase or receive back from a pharmacy a greater quantity of any prescription drug than was originally sold by the wholesaler except that when a pharmacy changes wholesalers, the new wholesaler may accept returns of product sold to the pharmacy by the previous wholesaler for a period of 60 days." This would address the initial returns following the change of wholesalers.

RESPONSE 26: The board acknowledges the comment. Based upon the comments received, the board has decided not to include sections (8) and (9) in the final version of ARM 24.174.1211.

COMMENT 27: A commenter stated that ARM 24.174.2401 should be amended to provide a specific procedure to be used if a board member is accused of wrongdoing, to provide for the specific appointment of an impartial panel composed of at least 50% nonboard members, and to allow the complainant and/or the licensee who is the subject of the complaint an opportunity to speak at the panel, if desired.

RESPONSE 27: As noted in Response 5, suggested substantive changes outside the scope of the proposed amendments must themselves be formally proposed by the board, appropriate notice given to interested persons and the public, and comment be allowed before the board can take final action on change. The board will keep the suggestions of the commenter in mind when it is contemplating future rule changes.

The board notes that it believes it is constrained by 37-1-307 and 37-1-131, MCA, to limit membership on a screening panel to persons who are board members. The board also notes that its members are subject to the ethical obligations of Title 2, chapter 2, part 1, MCA, as a public official or employee whenever serving in that person's official capacity as a board member. The board believes that it would be improper for a board member who has been named in a complaint to serve either on a screening panel or adjudication panel concerning a matter in which the member is named as the respondent.

COMMENT 28: The same commenter raised additional concerns that have been previously submitted to the board, namely the commenter's belief that screening panel meetings should be open to the public, and that complainants have a right to address the screening panel. The commenter also expressed the opinion that a public comment period should be part of every agenda.

RESPONSE 28: The board respectfully notes that the comments are not germane to the proposed amendments or new rules, and thus are outside the scope of this rulemaking proposal. However, the board offers the following general response:

The board believes that public participation is an essential feature of good government. At every public meeting conducted by the board, the board provides an opportunity for public comment, and the comment period is a regular agenda item. The board does not believe that meetings of the screening panel are public meetings, however. The screening panel has a function similar to that of a grand jury, namely deciding on whether there is reasonable cause to for the department to prosecute a complaint and proceed toward a formal disciplinary hearing. The board believes that unless the person named in a complaint as the respondent waives the right of individual privacy, that person's constitutional right of privacy, linked with a property interest as the holder of a professional license, outweighs the public right to know about the complaint, until such time as the screening panel makes a determination of "reasonable cause." In addition, there may be other circumstances present, especially in complaints related to health care professionals, to justify closing portions of a proceeding when the privacy rights of other involved individuals are concerned.

COMMENT 29: A commenter stated that once a screening panel was convened that did not meet the requirements of this rule, and the board was never "taken to task" for that, and questioned the need for the rule if it is being ignored. The commenter stated that the board needs to follow its own rules. The commenter also supports an additional panel to handle complaints against board members.

RESPONSE 29: Because the board recognized that the existing version of the rule did not provide for enough flexibility to adapt to unusual circumstances, the board proposed the amendments to ARM 24.174.2401. The board concludes that the proposed amendment adequately addresses the issue of flexibility to handle unusual circumstances where a panel member needs to be recused. As noted in Response 27, the board will keep the commenter's suggestions in mind when considering future amendments to this rule.

COMMENT 30: Comments were received regarding NEW RULE II stating the pharmacist to technician ratio should remain at 1:1 or be more stringent at telepharmacy sites.

RESPONSE 30: The board believes that it is not likely that there will be a need for more than one technician at a time in a telepharmacy location, but it agrees that if telepharmacy becomes a predominant form of delivery of prescriptions in the state, it will reconsider the wording of the rule. The board concludes that the present wording of “a registered pharmacy technician” means one technician.

COMMENT 31: A commenter suggested clarifying that NEW RULE II applies only to noninstitutional pharmacies.

RESPONSE 31: Because the board does not believe that NEW RULE II should apply only to noninstitutional pharmacies, the board is presently unwilling to make the suggested change. The board believes that there is no logical or legal basis to categorically exempt institutional pharmacies from application of the rule.

COMMENT 32: A commenter stated that the board lacks any authority to regulate competition and stated NEW RULE II should not have the ten-mile radius prohibition, which the commenter believes may prevent larger health care organizations from providing cost-effective telepharmacy service support, 24/7, to smaller hospitals and critical access hospitals and nursing homes.

RESPONSE 32: The board believes that it is not regulating competition by the adoption of NEW RULE II. The board believes that it is reasonable and appropriate to establish a set definition of what constitutes a "remote area" that is not served by a traditional pharmacy with a pharmacist present on-site. By establishing a ten-mile radius around an existing pharmacy, the board has made that definition by providing that the area within ten miles of an existing pharmacy is not eligible for a remote telepharmacy location. The board concludes that because its goal in allowing remote telepharmacy sites is to improve consumer access in unserved or under-served areas in Montana, NEW RULE II does not improperly limit competition. The board notes that the ten-mile restriction is unlikely to adversely affect a large hospital's relationship with a smaller hospital or critical access facility if that smaller facility is not already served by a nearby pharmacy.

COMMENT 33: A commenter suggested amending NEW RULE II(4)(g) to require that reports be generated upon request and that (4)(t) should clearly state that new prescriptions should be counseled and refills counseled if the pharmacist and patient feel it is necessary.

RESPONSE 33: The board agrees with comment regarding counseling and has amended NEW RULE II(4)(t) to clarify that requirement. With respect to (4)(g), the board's rule constitutes a request that reports be generated daily. The board believes that until such time as a clear history of remote location use and accuracy is established, daily reports are appropriate tools for both the provider and the board to use to determine the safety and effectiveness of the remote telepharmacy location.

COMMENT 34: A commenter stated that NEW RULE II does not address smaller hospitals' need to enhance provision of care and patient safety through remote pharmacist order reviewing during "off" hours of the pharmacy.

RESPONSE 34: The board agrees with the comment that NEW RULE II does not address smaller hospital's needs. To the extent that the commenter suggests that the board's rules be modified to take into account the desires of "smaller hospitals", the board will keep that request in mind when contemplating future rule changes.

COMMENT 35: The same commenter expressed the belief that computer, audio, and video links are not necessary for an inpatient order review in a telepharmacy setting.

RESPONSE 35: The board acknowledges the comment, but the board has not been presented with any evidence to demonstrate that less robust communication protocols are as safe and effective as the tri-modal communications systems required by the rule. In the absence of such evidence, the board respectfully declines the commenter's implied suggestion to allow elimination of one or more of the required components of the communication system between a parent location and the remote location.

COMMENT 36: The commenter stated that the requirements for maintenance of prescription records are not applicable to institutional pharmacies.

RESPONSE 36: The requirement of prescription record maintenance under NEW RULE II applies only in a telepharmacy relationship. If an institution operates a telepharmacy location, pursuant to the rule, then the rule applies. If the institution is not operating a telepharmacy location, the rule's requirements do not apply.

COMMENT 37: The commenter also asked that a rule be written to take into consideration non-24 hour pharmacies that use lock boxes and emergency dispensing provisions.

RESPONSE 37: The board will keep the request in mind when it considers additional rulemaking projects in the future.

COMMENT 38: Several comments were received regarding NEW RULE III. One commenter requested an exemption for remote institutional sites, such as hospitals, nursing homes, critical access hospitals, and detention facilities.

RESPONSE 38: The board will consider specific requests for a waiver for any particular facility on a case-by-case basis.

COMMENT 39: A commenter asked whether an independent pharmacy could place a dispensing machine at a physicians' clinic.

RESPONSE 39: Yes, if the clinic was not within a ten-mile radius of an existing pharmacy, and the clinic was willing to accept the dispensing machine on the premises.

COMMENT 40: A commenter suggested that the pharmacist in charge of a remote dispensing machine pursuant to NEW RULE III be responsible for ensuring monthly inspections are conducted and that different requirements for passwords be designed to keep up with current technology.

RESPONSE 40: The board believes facilities should develop security policies that fit their specific needs, but it declines to add the specific technological requirements suggested by the commenter. The board agrees that the pharmacist in charge is responsible for making sure that the remote dispensing machine is operated in a manner consistent with the rule.

COMMENT 41: A commenter stated she was reserving her comments on central fills (NEW RULE IV) until a later date when any ramifications are observable.

RESPONSE 41: The board acknowledges the diligence of the commenter and looks forward to future communication regarding the commenter's observations. The board notes, however, that comments received outside of the official comment period on these proposed rule changes cannot be acted upon by the board in this rulemaking project.

COMMENT 42: In reference to NEW RULE V, a commenter questioned how the board is held accountable to making rules in an expeditious fashion if it has had the authority (to make this rule change) since April 6,1999, and questions what has taken so long to create this rule.

RESPONSE 42: The board agrees that the legislative requirement for rulemaking should have been addressed earlier. The current board does not have a ready answer as to why previous boards did not undertake rulemaking on this topic. Each individual board member is appointed by the Governor to serve a five-year term. A board member may be removed by the Governor "for cause" pursuant to 2-15-124, MCA. The board notes that dereliction of duty may constitute "cause" for a governor to remove a board member.

COMMENT 43: Also in reference to NEW RULE V, a commenter stated concern with a physician director, as the facility would be board licensed, but the physician would not be. The commenter questioned whether the board could compel any changes in practice/compliance with this arrangement.

RESPONSE 43: The board notes that it merely registers ambulatory surgical facilities, and does not license them. The commenter is correct that the board does not have any direct regulatory authority over physicians (unless the physician also is licensed as a pharmacist). The board believes it has the authority to report diversions of drugs to the appropriate authorities. If the board has reason to believe that drugs are being diverted by a licensed health care provider, the board may report that information to the licensing board of that provider. If the facility is being operated in a manner inconsistent with the public health and safety, the board may report that to any governmental authority that regulates or licenses the facility.

COMMENT 44: A commenter proposed adoption of several new rules to address remote medication order processing, and provided suggested language for several new rules.

RESPONSE 44: New rules, as proposed by the commenter, would need to be noticed for public comment in a future rule notice. The board will consider including the requested rules when engaging in a future rulemaking project.

4. After consideration of the comments made, the board has amended ARM 24.174.301, 24.174.401, 24.174.403, 24.174.503, 24.174.514, 24.174.521, 24.174.522, 24.174.523, 24.174.524, 24.174.603, 24.174.705, 24.174.806, 24.174.814, 24.174.1002, 24.174.1111, 24.174.1201, 24.174.1202, 24.174.1212, 24.174.1401, 24.174.2101, and 24.174.2401 exactly as proposed.

5. After consideration of the comments made, the board has adopted NEW RULE I (24.174.504), NEW RULE III (24.174.1303), NEW RULE IV (24.174.822), NEW RULE V (24.174.1122), and NEW RULE VI (24.174.404), exactly as proposed.

6. After consideration of the comments made, the board has decided not to amend ARM 24.174.612.

7. After consideration of the comments made, the board has amended ARM 24.174.303, 24.174.711, 24.174.1107, 24.174.1211 with the following changes, stricken matter interlined, new matter underlined:

24.174.303 INTERNSHIP PROGRAM DEFINITIONS (1) through (5) remain as proposed.

(6) "Internship period" means 1500 hours of practical experience in an approved pharmacy, hospital, or other facility. The intern must acquire a minimum of 20 hours experience per calendar week and may acquire a maximum of 48 hours experience per calendar week. The student may acquire up to 1500 hours

concurrently with school attendance in approved courses, ~~externships~~ introductory pharmacy practice experience, and advanced pharmacy practice experience, or demonstration projects in the Pharm.D. program.

(7) through (9) remain as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

24.174.711 RATIO OF PHARMACY TECHNICIANS TO SUPERVISING PHARMACISTS (1) A registered pharmacist in good standing may supervise the services of no more than ~~four~~ three technicians at any time. The ~~1:4~~ 1:3 pharmacist to pharmacy technician ratio may be revised by the board at any time for good cause.

(2) Registered pharmacists in good standing in the state of Montana may supervise a maximum of ~~four~~ three registered pharmacy technicians, provided:

(a) through (c) remain as proposed.

(3) If a pharmacy desires more than ~~four~~ three technicians to work under the supervision, direction, and control of one pharmacist, the pharmacy shall obtain the prior written approval of the board. To apply for approval, the pharmacist-in-charge shall submit a pharmacy services plan to the board. The pharmacy services plan submitted shall demonstrate how the plan facilitates the provision of pharmaceutical care and shall include, but shall not be limited to the following:

(a) through (6) remain as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, 37-7-307, 37-7-308, 37-7-309, MCA

24.174.1107 ABSENCE OF PHARMACIST IN INSTITUTIONAL SETTINGS

(1) and (2) remain as proposed.

(3) A complete verification audit of all inpatient orders and activity concerning the night cabinet or after-hours pharmacy entry must be conducted by a pharmacist, pharmacy technician, or other licensed designee of that pharmacist within ~~48~~ 72 hours of the drugs having been removed from the night cabinet or pharmacy.

(4) and (5) remain as proposed.

(6) A copy of the original drug order with the NDC number or other identifying code of the drug(s) provided may be faxed to the pharmacist. If the patient is an inpatient, a patient profile containing the patient's name, location, allergies, current medication regimen, and relevant laboratory values must be reviewed by a pharmacist within ~~48~~ 72 hours.

AUTH: 37-7-201, MCA
IMP: 37-7-201, MCA

24.174.1211 MINIMUM REQUIREMENTS FOR STORAGE AND HANDLING OF DRUGS (1) through (7) remain as proposed.

~~(8) Within any calendar month, a wholesaler may not sell, distribute, transfer, or otherwise provide more than 10% of the total amount distributed of each prescription drug or drug product to another wholesaler, distributor, or manufacturer.~~

~~(9) A wholesaler may not purchase or receive back from a pharmacy a greater quantity of any prescription drug than was originally sold by the wholesaler.~~

AUTH: 37-7-201, 37-7-610, MCA
IMP: 37-7-604, MCA

8. After consideration of the comments made, the board has adopted NEW RULE II (24.174.1302) with the following changes, stricken matter interlined, new matter underlined:

NEW RULE II (24.174.1302) TELEPHARMACY OPERATIONS

(1) through (4)(s) remain as proposed.

(t) The pharmacist shall counsel the patient or the patient's agent via video and audio link on all new prescriptions, ~~and~~ but may provide counseling on refills only ~~if~~ when the pharmacist deems additional counseling necessary.

(u) through (z) remain as proposed.

AUTH: 37-7-201, MCA
IMP: 37-7-101, 37-7-201, 37-7-321, MCA

9. As noted in Response 13, the board has not yet taken final action with respect to the proposed amendments to ARM 24.174.801. The board will provide notice of its final action concerning the proposed amendments to ARM 24.174.801 at a later date.

BOARD OF PHARMACY
WILLIAM BURTON, R. Ph., CHAIRPERSON

/s/ MARK CADWALLADER
Mark Cadwallader
Alternate Rule Reviewer

/s/ KEITH KELLY
Keith Kelly, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State June 12, 2006